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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,143	JACKSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction / Election of Species

1) Claims 1-51 are under prosecution.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5, 6, 8 and 9, drawn to an NMASP polypeptide having the sequence comprising SEQ ID NO: 2, a homolog or fragment thereof, classified in class 530, subclass 350.

II. Claims 5, 6, 8 and 9, drawn to an NMASP polypeptide having the sequence comprising SEQ ID NO: 11, a homolog or fragment thereof, classified in class 530, subclass 350.

III. Claims 5, 6, 8 and 9, drawn to an NMASP polypeptide having the sequence comprising SEQ ID NO: 12, and a fragment thereof, classified in class 530, subclass 350.

IV. Claims 11 and 12, drawn to an antibody that specifically binds the NMASP polypeptide comprising a sequence of SEQ ID NO: 2, a homolog or a fragment thereof, classified in class 530, subclass 388.4.

V. Claims 11 and 12, drawn to an antibody that specifically binds the NMASP polypeptide comprising a sequence of SEQ ID NO: 11, a homolog or fragment thereof, classified in class 530, subclass 388.4.

VI. Claims 11 and 12, drawn to an antibody that specifically binds the NMASP polypeptide comprising a sequence of SEQ ID NO: 12, a homolog or fragment thereof, classified in class 530, subclass 388.4.

VII. Claims 39-45, drawn to an isolated DNA having SEQ ID NO: 1, and its corresponding fragment or complement thereof, classified in class 536, subclass 23.1.

VIII. Claims 39-45, drawn to an isolated DNA having SEQ ID NO: 10, and its corresponding fragment or complement thereof, classified in class 536, subclass 23.1.

IX. Claims 39-45, drawn to an isolated DNA having SEQ ID NO: 13, and its fragment or complement thereof, classified in class 536, subclass 23.1.

X. Claims 46 and 47, drawn to a method of producing an immune response comprising

immunizing an animal with the NMASP polypeptide having a SEQ ID NO: 2 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XI. Claims 46 and 47, drawn to a method of producing an immune response comprising immunizing an animal with the NMASP polypeptide having a SEQ ID NO: 11 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XII. Claims 46 and 47, drawn to a method of producing an immune response comprising immunizing an animal with the NMASP polypeptide having a SEQ ID NO: 12 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XIII. Claim 48, drawn to a plasmid from *E. coli*, classified in class 935, subclass 27.

XIV. Claim 50, drawn to an antagonist that inhibits the activity or expression of the NMASP polypeptide having a SEQ ID NO: 2, classified in class 530, subclass 300.

XV. Claim 50, drawn to an antagonist that inhibits the activity or expression of the NMASP polypeptide having a SEQ ID NO: 11, classified in class 530, subclass 300.

XVI. Claim 50, drawn to an antagonist that inhibits the activity or expression of the NMASP polypeptide having a SEQ ID NO: 12, classified in class 530, subclass 300.

XVII. Claim 49, drawn to a method for assaying an agent that interacts with NMASP polypeptide, classified in class 435, subclass 7.32.

XVIII. Claim 51, drawn to a method for identifying compounds which interact with the NMASP polypeptide having the sequence comprising SEQ ID NO: 2, and a fragment thereof, classified in class 435, subclass 7.2.

XIX. Claim 51, drawn to a method for identifying compounds which interact with the NMASP polypeptide having the sequence comprising SEQ ID NO: 11, and a fragment thereof, classified in class 435, subclass 7.2.

XX. Claim 51, drawn to a method for identifying compounds which interact with the NMASP polypeptide having the sequence comprising SEQ ID NO: 12, and a fragment thereof, classified in class 435, subclass 7.2.

Claims 1-4, 7 and 14-37 are linking claims and will be joined with one of inventions I, II and III, if elected.

Claims 10, 13 and 38 are linking claims and will be joined with one of inventions IV, V and

VI, if elected.

3) Inventions I through XX are distinct from one another. Inventions I-III, inventions IV-VI, inventions VII-IX, invention XIII, and inventions XIV-XVI, are drawn to distinct products: polypeptides; antibodies, nucleic acids, a plasmid, and antagonists. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically. A polypeptide is a single chain molecule which comprises amino acid residues. A DNA molecule comprises purine and pyrimidine units. Any relationship between a nucleic acid molecule and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While the polypeptides of inventions I-III can be made by methods of using the nucleic acids of inventions VII-IX, the polypeptides can also be made without using the nucleotide sequences of inventions VII-IX, i.e., by biochemical or synthetic means. For instance, the polypeptide can be produced by chemical synthesis. Antibodies are glycoproteins which include IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Furthermore, the polypeptides of inventions I-III, the antibodies of inventions IV-VI, the DNAs of inventions VII-IX, the plasmid from *E. coli* of invention XIII, and the antagonists that inhibit the activity or expression of the NMASP polypeptides of SEQ ID NO: 2, SEQ ID NO: 11, and SEQ ID NO: 12 of inventions XIV-XVI, are distinct molecules divergent with regard to their composition, structure, and function, each requiring a separate and non-coextensive search.

Furthermore, although the polypeptides of inventions I, II and III belong to the same class/subclass, the structurally distinct polypeptides comprising SEQ ID NO: 2, SEQ ID NO: 11, and SEQ ID NO: 12 respectively, require separate individual structural or sequence searches. Similarly, although inventions VII-IX belong to the same class/subclass, the DNAs of inventions VII-IX comprise sequences that are structurally or chemically distinct from one another, and require separate individual structural or sequence searches. Searching inventions I-III and inventions VII-IX together would impose a serious search burden. In the instant case, the search of the polypeptides and the nucleic acid molecules are not coextensive. Inventions I-III and inventions VII-IX have a separate status in the art as shown by their different classifications. In cases such as

this one, where descriptive sequence information is provided, the sequences are searched in appropriate amino acid and DNA databases. There is also search burden with regard to the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest, there may be journal articles devoted solely to polypeptides, which would not have described the nucleic acid molecules. Similarly, there may have been 'classical' genetics papers which had no knowledge of the polypeptides but spoke of the gene. The antibodies of inventions IV through VI differ from one another in their immunologic or binding specificity. The plasmid from *E. coli* belongs to class 435 and thus requires a separate search in a separate class.

Searching therefore is not coextensive.

4) Inventions X, XI, XII, XVII, XVIII, XIX and XX are drawn to distinct methods, which differ from one another in the product or reagent used therein, methods steps and parameters, method objectives, and ultimate goals used. The products used: (a) SEQ ID NO: 2; (b) SEQ ID NO: 11; (c) SEQ ID NO: 12; and (d) cells expressing NMASP, in the seven methods are divergent with regard to their structure and/or function, and classes/subclasses, each requiring separate and non-coextensive searches. The methods for identifying compounds or an agent are unrelated to the methods of producing an immune response in an animal by immunization. Therefore, searching the above-identified inventions together would not be coextensive and thus impose a serious search burden.

5) Inventions I and X, inventions II and XI, and inventions III and XII are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptides of inventions I, II and III respectively can be used in a materially different process, for example, as sources of coating antigens in an *in vitro* diagnostic assay to measure polypeptide-specific antibodies.

6) Inventions I and XVIII, inventions II and XIX, and inventions III and XX, are related as product and process of using the product. The inventions can be shown to be distinct if either or

both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptides of inventions I, II and III respectively can be used in a materially different process, for example, as sources of immunogens in laboratory animals to raise polypeptide-specific antiserum reagents.

7) Searching the inventions I and X, inventions II and XI, inventions III and XII, inventions I and XVIII, inventions II and XIX, and inventions III and XX together would impose a serious search burden. These inventions have a separate status in the art as shown by their different classifications. The search for inventions X, XI, XII, XVIII, XIX and XX would require a text search for the claimed methods in addition to a search for each product used therein. Moreover, even if each product were known, the methods, which use the products, may be novel and unobvious in view of the preamble or active steps.

Inventions IV-VI, inventions VII-XIX, and inventions XIII-XVI are unrelated to inventions X-XII and inventions XVII-XX, because the products of inventions IV-VI, the products of inventions VII-XIX, and the products of inventions XIII and XVI are not required to practice the methods of inventions X-XII and inventions XVII-XX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

8) If invention VII, VIII or IX is elected, Applicants must further elect: (a) the DNA species of SEQ ID NO: 1, SEQ ID NO: 10, or SEQ ID NO: 13, or (b) one of its corresponding DNA fragment or complement species claimed in claims 42 and 44.

9) Claims 3 and 4 are generic to a plurality of patentably distinct species comprising *Neisseria meningitidis* Type A, Type B, Type C, Type D, Type E, Type F, Type F, Type G, Type H, Type I, Type J, Type K, Type L, Type C or Type W. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct,

Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

11) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See '*Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. 37 CFR 1.143.

13) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

S. DEVI, PH.D.
PRIMARY EXAMINER

July, 2006